

Ivor M. Hughes

Barrister & Solicitor

*Patent & Trade Mark Agents
Canada, United States*



Our Ref: PT-2099001

September 12, 2005

VIA COURIER

The Commissioner of Patents
UNITED STATES PATENT OFFICE
Customer Service Window, Mail Stop Missing Parts
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Dear Sirs:

Re: United States Patent Application Serial No. 10/523,761
of Bernard Charles Sherman
for DUAL-SPIKE RELEASE FORMULATION FOR ORAL DRUG DELIVERY
Filed: February 7, 2005
CUSTOMER NO. 23607

Please be advised that we found an error in the Notice of Acceptance and Filing Receipt which we received in respect of the above-identified application.

In the Notice of Acceptance, a copy of which we are enclosing for your reference, the International Application Filing Date "**06/08/2003**" is incorrect. Please correct the International Application Filing Date in the Notice of Acceptance to read "**08/06/2003**".

In the Filing Receipt, a copy of which we are enclosing for your reference, the International Application Filing Date "**06/08/2003**" stated in the Domestic Priority data as claimed by applicant is incorrect. Please correct the Filing Receipt to read "**This application is a 371 of PCT/CA03/01175 08/06/2003**".

We kindly ask that the Notice of Acceptance and Filing Receipt be corrected to reflect the correct International Application Filing Date.

We thank the Commissioner for his co-operation in this regard, and look forward to receiving the correct Notice of Acceptance and Filing Receipt in this matter.

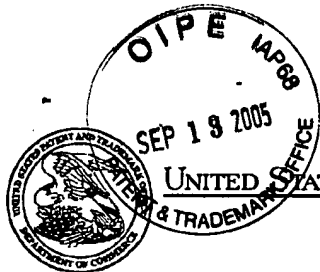
Respectfully submitted

Neil H. Hughes, P. Eng.
Registration No. 33,636
Agent for Applicant

NHH/lvp
Enclosures

IPW
Barristers & Solicitors
Ivor M. Hughes
Rick Tuzi

Patent Agents
Neil H. Hughes, P.Eng.
Marcelo K. Sarkis, P.Eng.
Wm. Kitt-Sinden
Samuel T. Tekie, P.Eng.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/523,761	FIRST NAMED APPLICANT Bernard Charles Sherman	ATTY. DOCKET NO. PT-2099001
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INTERNATIONAL APPLICATION NO. PCT/CA03/01175

23607
 IVOR M. HUGHES, BARRISTER & SOLICITOR,
 PATENT & TRADEMARK AGENTS
 175 COMMERCE VALLEY DRIVE WEST
 SUITE 200
 THORNHILL, ON L3T 7P6
 CANADA

I.A. FILING DATE 06/08/2003 08/06/2003	PRIORITY DATE 08/13/2002
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CONFIRMATION NO. 1380
 371 ACCEPTANCE LETTER



Date Mailed: 07/14/2005

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

<u>02/07/2005</u>	<u>02/07/2005</u>
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Copy of the International Application filed on 02/07/2005
- Copy of the International Search Report filed on 02/07/2005
- Copy of IPE Report filed on 02/07/2005
- Copy of Annexes to the IPER filed on 02/07/2005
- Preliminary Amendments filed on 02/07/2005
- Information Disclosure Statements filed on 02/07/2005
- Oath or Declaration filed on 02/07/2005
- Request for Immediate Examination filed on 02/07/2005
- U.S. Basic National Fees filed on 02/07/2005
- Priority Documents filed on 02/07/2005
- Power of Attorney filed on 02/07/2005

- Specification filed on 02/07/2005
- Claims filed on 02/07/2005

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

KAYA L LEWIS BALTIMORE
Telephone: (703) 308-9140 EXT 202

PART 1 - ATTORNEY/APPLICANT COPY

FORM PCT/DO/EO/903 (371 Acceptance Notice)



UNITED STATES PATENT AND TRADEMARK OFFICE

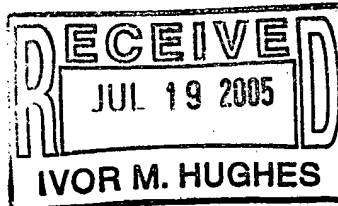
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 Alexandria, Virginia 22313-1450
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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/523,761	02/07/2005	1645	1260	PT-2099001		8	1

CONFIRMATION NO. 1380

23607
 IVOR M. HUGHES, BARRISTER & SOLICITOR,
 PATENT & TRADEMARK AGENTS
 175 COMMERCE VALLEY DRIVE WEST
 SUITE 200
 THORNHILL, ON L3T 7P6
 CANADA

FILING RECEIPT



OC000000016488701*

Date Mailed: 07/14/2005

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Bernard Charles Sherman, Toronto, CANADA;

Power of Attorney: The patent practitioners associated with Customer Number 23607.

* Domestic Priority data as claimed by applicant

This application is a 371 of PCT/CA03/01175 ~~06/08/2003~~

08/06/2003

Foreign Applications

CANADA 2,395,819 08/13/2002

Projected Publication Date: 10/20/2005

Non-Publication Request: No

Early Publication Request: No

Title

Dual-spike release formulation for oral drug delivery

Preliminary Class

424

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).